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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,410	04/12/2001	Toyohiro Sawada	019941-000510US	3651

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 09/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/834,410	Applicant(s) SAWADA ET AL.	
	Examiner Micah-Paul Young	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-26 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1- 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakashima et al (EP 0 661 045) in view of Taniguchi et al (EP 0 709 386) both in further view of Wong et al (USPN 5,391,381) and Kawata et al (USPN 4,404,183). Claims 1 – 20 and 23 – 26 are drawn to a time-released compressed layered tablet. The core comprises erodible fillers, while the outer layer is made from a hydrogel-forming polymer and a hydrophilic base. The erodible filler is selected from malic, citric and tartaric acid, polyethylene glycol sucrose, and lactulose. The hydrogel-forming polymer contains a type of polyethylene oxide. The hydrophilic base is selected from polyethylene glycol sucrose, and lactulose. Claims 21 – 24 are drawn to method of alleviating drug interactions.

Nakashima discloses essential elements to the claims invention. The reference discloses a compression-molded tablet comprising a hydrogel-forming polymer and a hydrophilic base. The tablet of Nakashima also contains a drug. The disclosure recites various drugs ranging from anti-inflammatory agents to central nervous system drugs such as idebenone. Also the tablet is formulated to release or be absorbed in the lower digestive system (pg. 3, lin. 25 – 35). Polyethylene glycol and polyethylene oxide are used as the hydrophilic base/hydrogel-forming polymer used in the tablet of Nakashima (Examples).

Though Nakashima discloses essential elements of the claimed invention, it is deficient is some ways. First the tablet of the reference is silent to a specific erodible core. However, the center of the compressed tablet does contain polyethylene glycol, which is defined by applicant to be suitably erodible, and has identical solubility properties (pg. 3, lin. 49 – 56). The elements surrounding said core are the polyethylene glycol/oxide combination of the preparation. Another deficiency in the reference is its silence to the specific drug and properties associated with it. Also Nakashima does is silent to the inclusion of red or yellow ferric oxide into the preparation. Though the reference does suggest the optional inclusion of additional colorants, binders, etc., red or yellow ferric oxide is not named. The inclusion of re and/or yellow ferric oxide into pharmaceutical formulations is common in the art as seen in Wong et al, where the tablet preparation includes a polyethylene oxide and red ferric oxide (examples).

With regard to the active agent, Nakashima discloses that drugs ranging from anti-inflammatory agents to CNS effecting agents can be used in the preparation. Taniguchi discloses a fused benzazepine derivative, which can be useful as a vasopressin antagonist. The drug can be formulated into tablets using conventional excipients such as sucrose, gelatin and

hydroxypropylcellulose (pg. 27, lin. 23 – 37). The drug of the invention can be used in the treatment of various disorders ranging from cerebrovascular disease to renal disorders (pg. 23, lin. 24 – 44).

With regard to claim 3, which recites the specific concentrations of the constituents, these limitations are seen as non-critical to the patentability of the claimed invention. The prior art teaches a tablet with an erodible core, a surrounding of a hydrophilic base and a hydrogel-forming polymer, and a drug. The general combination of these constituents in taught in the prior art. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller,* 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various pharmaceutical compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *In re Russell*, 439 F.2d 1228, 169 USPQ 426 (CCPA 1971).

With regard to claims 5 and 6, which recite the erodible fillers suitable for the invention, it is the position of the examiner that these limitations do not distinguish the claimed invention from the prior art. Malic, citric and tartaric acid are common excipients in sustained release formulations, as carriers of pharmaceutical agents or fillers such as hydroxypropylcellulose. This can be seen in Kawata et al which discloses sustained release tablet formulation comprising polyethylene glycol, polyethylene oxide as a coating and citric acid as carrier (examples).

With regard to claims 15 – 19, which recite various characteristics of the active agent, it is the position of the examiner that these claims are non-critical to the patentability of the claimed invention. The properties are inherent to the formulation of Taniguchi, the drug of claims 20 and 26, and thereby do not distinguish the claimed invention from the prior art.

With regard to claims 24 and 25, which recite improvements comprising the preparation as previously described by applicant, it is the position of the examiner that these claims are too obviated by the prior art. Nakashima provides the compression molded hydrophilic base/hydrogel-forming polymer tablet. The core of the tablet of Nakashima comprises polyethylene glycol, which possesses sufficient erosion and solubility properties to carry out the modes of the invention. Given the wide range of drugs useful with the preparation, one of ordinary skill in the art would be able to incorporate a drug into the core and another into the surrounding area. Though a percentage of erosion is not recited, this erosion is inherent to the excipient chosen, and can be further refined through routine experimentation.

With these aspects in mind one of ordinary skill in the art would have been motivated to combine the suggestions and teachings in the art. A skilled artisan would have been motivated to combine the hydrophilic base/hydrogel-forming polymer preparation with the drug of Taniguchi in order to provide a sustained release profile for the drug to the lower intestinal tract. Following the knowledge on the art the skilled artisan could have substituted any number of excipients including those of Wong or Kawata into the preparation in order to add an aesthetic appeal or better erosion properties. It would have been obvious to one of ordinary skill in the art, at the time of the invention to combine these teachings and suggestion in this way, with an expected

result of sustained release oral tablet capable of treating various renal and cardiovascular disorders.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am-4: 30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MPY
September 9, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600